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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

NOTIFICATION DATE	DELIVERY MODE
05/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/825,955	HERUTH ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-27 and 69-71* is/are pending in the application.

4a) Of the above claim(s) *7,10,13,22-24,26,27 and 69-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,11,12,14,15,17-21 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date:

07/30/2007, 09/18/2007, 12/21/2007, and 01/16/2008.

DETAILED ACTION

1. As an initial matter, the Examiner vacates paragraph 14 of the Detailed Office Action mailed 06/27/2007. See Examiner's Interview Summary mailed 10/01/2007.

Election/Restrictions

2. Applicant's election with traverse of Species AAA in the reply filed on 02/21/2008 is acknowledged. The traversal is on the ground(s) that the Species AAA and BBB (a) are not mutually exclusive, and/or (b) are not independent or distinct because they are not substantially dissimilar and structurally divergent means for configuring a medical device to evaluate and/or affect a patient's sleep, and (c) that claim 1 is generic. This is not found persuasive because (a) the "monitoring embodiment" does not require delivering therapy as set forth in the specification in describing the "therapy embodiment", (b) the "monitoring embodiment" does not affect a patient's sleep as set forth in the specification in describing the "therapy embodiment", and (c) claims 1 does not positively recite any steps in the method of providing a "therapy" or affecting a patient's sleep.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 22, 23, 26, 27, 69, and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/21/2008.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. This application contains claims 7, 10, 13, 22, 23, 24, 26, 27, 69, 70, and 71 drawn to nonelected inventions in the replies filed on 06/30/2006 and 02/21/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

6. The information disclosure statement(s) (IDS) submitted on 07/30/2007, 09/18/2007, 12/21/2007, and 01/16/2008 is/are acknowledged. The submission(s) is/are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-21 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US 2004/0111040 A1).

9. Claims 1-3, 5, 6, 8-9, 11-12, 14-15, 17-21, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 2004/0111041 A1).

10. For claim 1, Ni et al discloses a method, comprising:

- monitoring a plurality of physiological parameters (620, 625, and 630) of a patient via an implantable medical device (100, 200 and 300), wherein the plurality of

physiological parameters includes at least one parameter indicative of patient physical activity (e.g. at least breathing or posture) (paragraphs 39, 52, and 77);

- determining when the patient is attempting to sleep via sensors (130, 134, 320, and 321) (as best seen in Figures 5B and 6) (paragraphs 7, 11, 53-57, 77, and 84-90);
- determining values of at least one sleep quality metric (550) that is indicative of sleep quality based on values of the at least one physiological parameters when the patient is attempting to sleep (565) (as best seen in Figure 5A) (paragraphs 47-48, 53-57, and 84-90);
- periodically determining an activity level (paragraphs 42-43 and 51) of the patient based on the at least one physiological parameters and a determination that the patient is not attempting to sleep (570) (paragraph 106);
- determining a value of at least one activity metric based on the activity levels determined when the patient is not attempting to sleep (paragraphs 132-134); and
- associating the sleep quality metrics and the activity level metrics with a therapy parameter set (587 and 597) via elements 340 and 350 (paragraphs 62-63 and 72).

11. For claim 2, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the patients sensed activity levels as cited above) that the patient is attempting to sleep (paragraph 106).

12. For claim 3, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep

comprises determining when the patient is recumbent (as best seen in Figures 5B and 6) (paragraphs 97, 106, and 119).

13. For claims 5 and 6, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (Figures 5B and 6) (paragraphs 11, 77, and 95-97) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (paragraphs 48, 57, 84-85 and 95).

14. For claims 8 and 9, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood pressure (paragraph 52).

15. For claim 11, Ni et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the physiological parameters; and determining an amount of time between the first and second times (as best seen in Figures 7A, 7B9, 14, and 15).

16. For claim 12, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is asleep based on at least one of the physiological parameters (510); and determining an amount of time that the patient is asleep during a period (as best seen in Figures 7A, 7B9, 14, and 15).

17. For claim 14, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is within a sleep state based on at least one of the physiological parameters (510); and determining an amount of time that the patient was within the sleep state (as best seen in Figures 7A, 7B9, 14, and 15).

18. For claim 15, Ni et al discloses a method wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state (paragraphs 2-4).

19. For claim 17, Ni et al discloses a method wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels (paragraphs 46 and 99).

20. For claim 18, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing the at least one of the mean and the median activity level to at least one threshold (paragraph 99); and selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison (paragraphs 47 and 92).

21. For claim 19, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining at least one of a percentage of time above the threshold and a percentage of time below the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

22. For claim 20, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining an average length of time that consecutively determined activity levels were

above the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

23. For claims 21, Ni et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (as best seen in Figures 7A, 7B9, 14, and 15);

24. For claim 25, Ni et al discloses a method wherein a medical device comprises an implantable medical device (paragraph 11).

Claim Rejections - 35 USC § 103

25. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

26. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al in view of Sheldon (US 5,593,431). Ni et al discloses the claimed invention, including monitoring posture via accelerometers, except for explicitly disclosing monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals. Sheldon teaches a medical device comprising monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device as taught by Ni et al, with the medical device as taught by Sheldon for the purpose of monitoring posture.

Response to Arguments

27. Applicant's arguments filed 10/26/2007 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of at least claims 1, 6, 11, and 19 under Ni, specifically arguing Ni fails to disclose, teach, and/or fairly suggest: (a) “determining when a patient is attempting to sleep”, (b) “comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold”, (c) “identifying a first time when the patient is attempting to fall asleep” and "identifying a second time when the patient falls asleep" for “determining an amount of time between the first and second time”, and (d) “determining a percentage of time above or below a threshold” based on a comparison of activity levels to a threshold value. The Examiner disagrees, maintains the rejection as reiterated above, and notes the following in response:

28. For Applicant’s argument that Ni fails to disclose (a) “determining when a patient is attempting to sleep”, the Examiner notes Ni is expressly concerned with and discloses monitoring the waking and sleeping activity of a patient as posture (paragraphs 77, 90, 97-98, and 106) and in addition basing the determination of when a patient is attempting to sleep on the time of day (paragraph 87).

29. For Applicant’s argument that Ni fails to disclose (b) “comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold”, the Examiner notes Ni is expressly concerned with and discloses comparing activity levels to threshold values (paragraphs 48, 57, 84-85 and 95) and

establishing the amount of time above and/or below said threshold (paragraph 94) (as best seen in Figures 7A, 9, 11-12, 14, and 15).

30. For Applicant's argument that Ni fails to disclose (c) "identifying a first time when the patient is attempting to fall asleep" and "identifying a second time when the patient falls asleep" for "determining an amount of time between the first and second times", the Examiner notes Ni is expressly concerned with and discloses determining an amount of time between said first and second times (paragraph 94) (as best seen in Figures 7A, 9, 11-12, 14, and 15).

31. For Applicant's argument that Ni fails to disclose (d) "determining a percentage of time above or below a threshold" based on a comparison of activity levels to a threshold value, the Examiner notes Ni is expressly concerned with and discloses percentages of time above or below a threshold times (paragraph 94) (as best seen in Figures 7A, 9, 11-12, 14, and 15).

Conclusion

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736